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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/608,892	06/30/2000	Perry D. Haaland	P-4948	2067

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EXAMINER

BHATTI, TAHIRA H

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 04/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/608,892	Applicant(s) HAALAND ET AL.	
	Examiner Tahira H Bhatti	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 5-11 and 19-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Receipt is acknowledged of raw sequence, statement, election and election of species, filed on 6/17/00, 6/30/00, 1/9/02 and 3/21/02.

DETAILED ACTION

Status of the Claims:

1. Claims 1-30 are pending.
2. Applicant's election without traverse of group I (claims 1-4 and 12-18)
In Paper No. 5 is acknowledged.
3. Claims 5-11 and 19-30 are withdrawn from consideration due to,
Election restriction requirement.
4. The applicant further elects without traverse the following species,
 - a. Penta-peptides
 - b. SEQ ID NO: 16, (FEFVG) in a Supplemental Document to the response of Restriction Requirement filed by the applicant on 3/21/02. in paper No: 6, is acknowledged.
5. The species election for one peptide sequence has been withdrawn, in view of the elected SEQ ID NO: 16 is free of prior art. The search has been extended to the other peptides.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1-4 and 12-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pentpeptide of SEQ ID NO: 16, does not reasonably provide enablement for any other peptides in the concatemers preparation. The specification does not provide sufficient information for specific cites and specific enzymatic means to release SEQ ID NO: 16 from the prepared concatemer. Given the nature of the invention, the breadth of the claim, the scarcity of guidance and working examples in the specification, and the unpredictable nature of the art, it would require undue experimentation for one skilled in the art to make and use the full scope of the claimed invention.

The factors to be considered in a determination of undue experimentation are disclosed in In re Wands (USPQ 2d 1400: CAFC 1988), which include: a. The breadth of the claims. b. The nature of the invention. c. The state of the prior art. d. The level of one of ordinary skill. e. The level of predictability in the art. f. The amount of direction provided by the inventor. g. The presence or absence of working examples h. The quantity of experimentation necessary needed to make or use the invention based on the disclosure. See :In re Wands USPQ 2d 1400 (CAFC 1) a.

The breadth of the claims: The breadth of potential for producing and identifying a peptide, exhibiting biological activities, produced by expression of a recombinant nucleic acid sequence encoding the peptide and further producing a concatemer of the peptide, cleavable by enzymatic means to release the peptide monomers, is broad in light of the failure to specifically claim, for isolating,

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characterizing and identifying the peptide with a specific structure, and the concatemer of SEQ ID NO: 16 or other peptides, in relation to the specific position of the amino acids in the monomers and their chemical property.

The nature of the Invention/State of the Prior Art: The present invention as claimed is broadly directed to producing a peptide by expression of a recombinant nucleic acid sequence encoding the peptide in a cell or tissue culture medium. It is noted that the nature and placement of the cells in the culture medium, which is critical to allow evaluation of the peptide effect (claims 2, 3, and 4), is a complex medium. See spec. page 5, lines 11-13. The applicant has failed to identify the cells and the defined cell culture media. Additionally it is further noted that these peptides are used as probes to identify the presence of a specific compound which exhibit a biological function (spec. page 3 lines 1-2.) which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure.

The amount of direction/working examples: The specification only provides guidance and examples directed to selecting and identifying peptides. This does not provide enough guidance as to the specific steps of biological activity of the penta-peptide of SEQ ID NO: 16, or any other peptide (i.e. binding, enhancing or inhibiting activity of peptides), and does not specify and provide enough guidance of the peptide in relation to cell types and cell culture. This is not representative of the scope of claimed methods, to select and identify peptide with binding, inhibiting, or enhancing, activity.

Quantity of Experimentation: Due to the lack of representative examples regarding the peptides and their activities the amount of experimentation would be undue.

Accordingly, in light of the unpredictability surrounding the method selecting a peptide for enhancing and inhibiting activity, which would also participate in identifying biologically active compounds, the undue breadth of the claimed invention, the lack of adequate guidance, the lack of metes and bounds regarding claimed constituents, one wishing to practice the presently claimed invention would be unable to do so without engaging in undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4 and 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. The "concatemer of the peptide" (claim 3), "chemically defined medium" (claim 17) can "comprises about " (claims 18), are vague, they encompass enormous field, and in the specification there is a lack of directional guidance for specificity. It is unclear as what the chemically defined medium is, and the specification does not give sufficient information about the chemically defined medium.

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Claim 3 recites, "cleavable by enzymatic means", sufficient information on specific site of cleavage and consequently the monomer produced which needs to be identified and characterized is lacking.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 12-18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Suzuki, U.S. Patent No: 5,464, 819.

Suzuki discloses an active peptide produced in large quantities by recombinant techniques and formulated in culture medium to produce the desired effect on cultured cells and tissues. The '819 reference further discloses that the peptides identified are particularly useful in concatamer-based recombinant expression methods. The '819 reference also discloses, at least one peptide selected from the group consisting of pure physiologically active peptides comprising amino acid SEQ ID NO: 3, which corresponds to SEQ ID NO: 85 of the instant claims, 1 and 16. Accordingly the '819 reference clearly teaches the peptide within the scope of the presently claimed invention. See the entire document, specifically the abstract.

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10. No claims are allowed.

11. ***General information regarding further correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Tahira Bhatti whose telephone number is (703) 605-1203. The examiner can normally be reached between Monday to Friday from 8:00 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsana Venkat (art unit 1627), can be reached at (703) 308 0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (702) 308-0196

Tahira Bhatti (art unit 1627)

May 17, 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER